Exhibit Q

Acceptance Program
Guidelines

Toothbrushes

ADA American Dental Association
Council on Scientific Affairs 2006

Council on Scientific Affairs

Toothrushes

Scope:

These guidelines apply to both manual and powered toothbrushes. Whenever toothbrushes are mentioned, it refers to both manual and powered. These guidelines also cover specialty brushes, e.g. infant toothbrushes.

I. SUBMISSION DIRECTIONS

1. General Information

A Submissions are to be sent to the Council Office:
Director, Product Evaluations
Council on Scientific Affairs
American Dental Association
211 East Chicago Avenue
Chicago, Illinois 60611-2678

B Refer to instructions in the submission packet as to the numbers of submission CDs and print copies required. CDs should be indexed with hyperlinks to supporting documentation. Submission packets can be obtained by calling (312) 440-3528. If possible, the submission should be less than 200 pages exclusive of appendices.

C Submit a market sample of each product under evaluation and packaged as marketed. The Council agrees to return the product sample within six months if requested.

D A manufacturer is advised that the review process is complex. Typically, notification of Council action may be expected 90 to 150 days from the receipt of a complete submission by the Council. More time may be required if additional information or clarification is needed from the manufacturer.

E When a product is classified as "Accepted," the classification is for 5 years. Renewal of the classification will be considered by the Council upon request by the manufacturer.

F Classification of a product under the Acceptance Program is subject to the conditions stated in the Agreement Governing Use of ADA Seal of Acceptance.

2. Arrangement of a Submission

A The submission is to be divided into sections and arranged in order as indicated in part II. Sections to be identified by tabs are designated by an asterisk (*).

II. INFORMATION TO BE SUBMITTED

1. **Cover Page**

   A Name of company

   B Product name

*2. **Table of Contents**

*3. **Company Information**

   A Name of company (to be used in listing)

   B Address (to be used in listing)

   C Phone number (to be used in listing)

   D Fax number

   E Names of owners, officers and other individuals authorized to furnish information to the Council and represent the firm in dealing with the Council.

   F Names and qualifications of scientific personnel responsible for formulation and testing of the product in its manufacturing process.

*4. **Summary of Submission**
Comprehensive summary of all information on safety and effectiveness of the manual or powered toothbrush.

*5. **Product Information**

   A Name of product (to be used in listing). A separate submission will be required for each variation in brush design that could affect the safety or efficacy of the brush. It is the responsibility of the manufacturer of the submitted product to provide appropriate information so that a particular design change does not require a separate submission.

   B Claims of efficacy and safety
   (i) Claims for the toothbrush in labeling and in advertising shall generally be limited to those related to oral cleanliness. Toothbrushes which meet these guidelines will also be able to make claims such as "removes plaque" and "reduces gingivitis." Any claims beyond this will require additional laboratory and/or clinical studies.
   (ii) Advertisements must avoid disparagement of other toothbrushes.

   Note: For further discussion on the Council's position on the relationship between plaque and gingivitis, see the Council's Guidelines for Acceptance of Chemotherapeutic Products for the Control of Gingivitis, 1997.

   C Patent title(s) and patent number(s) relating to the product

   D Product description
   (i) List the materials used in the construction of the product
   (ii) Principles of design

   E Labeling

   F Packaging

G Promotional materials

•6. **Quality Control Procedures for the Manufacturing of the Product**

•7. **Safety Data**

A Evidence must be provided that the components of the toothbrush are safe for use in the oral cavity. Components and colorants should comply with applicable FDA standards (where appropriate).

B Toothbrush bristles shall be free of sharp or jagged edges and endpoints.

C In relation to bristle stiffness, reference should be made to the test methods in ISO 22254 (2005). Following the method described in Appendix A of ISO 22254 (2005), brushes having a stiffness index greater than 6 will usually not be considered for Acceptance. If the measured stiffness index is found to be greater than 6, clinical data demonstrating the safety of a toothbrush's bristles will be required (See Clinical Protocol Guidelines). In addition, abrasivity testing should be conducted using a toothbrush brushing machine (see ISO 11609:1995, Annex A).

D Manual toothbrushes shall comply with the requirements of ISO 20126 (2005).

E For powered toothbrushes, the product must have been submitted to an examination by and met the requirements of an appropriate technical safety laboratory such as Underwriters Laboratories, Inc. This requirement may be waived for products operating from non-rechargeable batteries of low voltage. The product shall also comply with the requirements of ISO 20127 (2005).

F For powered toothbrushes, adequate evidence must be provided from at least one clinical investigation of at least 25 subjects per group to show that the product is safe to oral hard and soft tissues and dental restorations (See Clinical protocol guidelines).

•8. **Efficacy Data-Clinical Data to Show Effectiveness**

A Manual toothbrushes
(i) Clinical studies will normally not be required for manual toothbrushes if they meet the above guidelines for safety and claims of efficacy. If the product does not meet the guidelines for safety then a 90 day clinical trial will be required (See Clinical Protocol Guidelines).
(ii) New technology: If in the opinion of the Council the toothbrush involves completely new technology then the guidelines given below apply (See Section 8B).

B Powered toothbrushes

Adequate evidence must be provided from at least one clinical investigation of at least 25 subjects per group to show that the product can be employed under unsupervised conditions by the average layman to provide a 15% statistically significant reduction versus baseline in gingivitis and a statistically significant reduction in plaque (see Clinical protocol guidelines).

C Specialty toothbrushes

This category, for example, covers infant toothbrushes not based on an adult product. Infant brushes based on an Accepted adult product will not require additional clinical evidence for Acceptance.

Adequate evidence must be provided from at least one clinical investigation of at least 25 subjects per group to show that the product can be employed under unsupervised conditions by the average layman to provide a 15% statistically significant reduction versus baseline in gingivitis and a statistically significant reduction in plaque (see Clinical protocol guidelines).

•9. **Comprehensive Bibliography**

•10. **Copies of Most Significant Articles**

*11. **Appendices**
Evaluation forms, detailed description of test evaluation methods and any other defined areas.

III. REQUIREMENTS (PERFORMANCE CRITERIA) FOR CLASSIFICATION OF "ACCEPTED":

The toothbrush must meet all of the safety, efficacy and claims of efficacy requirements as specified above.

IV. STATEMENT TO BE USED FOR PRODUCTS CLASSIFIED UNDER THESE GUIDELINES:

"The ADA Council on Scientific Affairs Acceptance of (Product Name) is based on its finding that the product is effective for removing plaque and helping to reduce or prevent gingivitis, when used as directed."

V. REFERENCES

ADA Acceptance Program Guidelines for Chemotherapeutic Products for Control of Supragingival Gingivitis, 1997.
ADA Acceptance Program Guidelines for Clinical Trial Protocols, 2003.
ISO 22254, Dentistry -- Manual toothbrushes -- Resistance of tufted portion to deflection, 2005.
ISO 11609, Dentistry –Toothpastes—Requirements, test methods, and marking, 1995.
ISO 20126, Dentistry -- Manual toothbrushes -- General requirements and test methods, 2005.
ISO 20127, Dentistry -- Powered toothbrushes -- General requirements and test methods, 2005.

CLINICAL PROTOCOL GUIDELINES

The following guidelines are given for the design and conduct of clinical studies using manual or powered toothbrushes to provide evidence of safety and effectiveness in cleaning teeth and reducing a disease process (e.g., gingivitis). Additional information concerning clinical trials and clinical trial reporting can be obtained from the Council's Guidelines for Clinical Trial Protocols (See V. References). Manufacturers are encouraged to submit their clinical protocols to the Council for review prior to the start of clinical studies.

Sample Size: At least 30 subjects for each product will be entered into the study at baseline. At least 25 patients for each product will be available for examination at the end of the study. Each subject will have a complete oral cavity examination to determine eligibility for the study. In general, subjects should be adults of normal health with mouths free from major hard or soft tissue lesions. Entry criteria should avoid patients with advanced or non-representative disease states. It is recommended that subjects with mild to moderate gingivitis be selected. The control toothbrush to be used in the study will be provided by the Council.

Study Duration: The study will be conducted for a least a 30-day period. However, for toothbrushes which do not meet the bristle stiffness index requirements of Section 7c the safety assessments (see below) should be continued for a total of 90 days. Measurements will be taken at least at BASELINE (prior to the study), 15 days (optional), and at 30 DAYS (and at 90 days for products not meeting the requirements of Section 7c).

Safety Assessments: Safety assessments will be made at each measurement period. Areas to be examined will be the tongue, hard and soft palate, gingivae, mucobuccal folds, the inner surface of the cheeks and sublingual space areas. Any effects on hard tissue and/or dental restorations should be reported. In particular, the cervical root area will be carefully examined.

Plaque Assessments: Plaque will be scored before and after brushing at each examination using a well-recognized plaque index (e.g., Turesky et al) *(J. Periodont 41:41,* 1970). Justification for the particular plaque index used must be provided. Full mouth plaque evaluations should be performed. The index used shall measure plaque at gingival areas of at least the facial, lingual and interproximal areas of the teeth.

Gingivitis Assessments: Gingivitis will be evaluated using a well-recognized gingival index; e.g. Löe and Silness *(Acta Odontol Scand.* 21:533, 1963). Justification for the particular gingival index used must be provided. Full mouth evaluations should be performed. Evaluations will include measurements at the papillae area of the gingival margin. The Council realizes that if subjects without appreciable gingivitis are selected for the study, they may not demonstrate a 15% reduction in gingivitis during the course of the study. For purposes of Acceptance of products intended to improve gingival health, however, the Council believes that it is reasonable to require a demonstration of a meaningful reduction in gingivitis. Therefore, patients with mild to moderate gingivitis should be selected (see above section on sample size).

Clinical Procedure: On each examination day (e.g., baseline, 15 days (optional), 30 days, (90 days if necessary)) the subjects will report having not cleaned their teeth for 12-16 hours (overnight plaque formation). Safety, plaque and gingivitis evaluations will then be made. Between the baseline and 30 days (90 days, if necessary) examination, each subject will be instructed to brush his/her teeth daily, using the test toothbrush and an assigned fluoride dentifrice. No other dental cleaning aids such as dental floss will be permitted during the study period.

Statistical Analysis: Mean group scores for plaque and gingivitis on all surfaces will be compared at baseline, 15 days (optional) and 30 days (90 days, if necessary) with either a parametric or non-parametric test for matched pairs. If more than two groups are being evaluated, appropriate multiple comparison tests should be used. Where appropriate, a non-parametric test will be used to assess the safety evaluation data (normal vs. abnormal).

Notes:

1 It is desirable to provide a measure of intra- and inter-evaluator variance.

2 An attempt should be made to assess the level of compliance of the subjects in the study. Examination of toothbrush condition at the conclusion of the study is one method of attempting this assessment.

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